



PATENT
Docket No. C 2272 COGG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Gerhard Wollmann, et al.

Serial No. 09/923,629

Filed: 08/07/01

Examiner: Barbara P. Badio, Ph.D.

Art Unit: 1616

TITLE: PROCESSES FOR PRODUCING STEROLS FROM FATTY ACID PRODUCTION
RESIDUES

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Respectfully submitted,

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BY: Rose A. Stowe DATE: March 15, 2004
Rose A. Stowe

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of Gerhard Wollmann, <i>et al.</i>	: Group Art Unit: 1616 : : :
Appln. No.:	09/923,629	: Examiner: Barbara P. Badio, Ph.D. : :
Filed:	August 7, 2001	: Confirmation No.: 2062 : :
For:	PROCESSES FOR PRODUCING STEROLS FROM FATTY ACID PRODUCTION RESIDUES	: Attorney Docket : No.: C 2272 COGG :

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Pursuant to the Notice of Appeal filed on November 13, 2003, via facsimile, and received by the U.S. Patent & Trademark Office on the same date, Appellants submit herewith a Brief On Appeal under 37 C.F.R. §1.192, appealing the Examiner's final rejection of pending claims 1-9 and 13-31 as set forth in the final Office Action dated July 15, 2003 (Paper No. 10), as maintained in the Advisory Action dated October 28, 2003 (Paper No. 12). This Brief On Appeal is being timely filed as a Petition for a two-month extension of time, up to and including March 15, 2004 (March 13, 2004 being a Saturday), including an authorization to charge fees, is being submitted herewith.

Appellants respectfully request consideration by the honorable Board of Patent Appeals and Interferences and reversal of the Examiner's rejections based on the arguments set forth in the attached brief.

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REAL PARTY IN INTEREST

The real party in interest in the instant appeal is Cognis Deutschland GmbH & Co. KG, a German company having a place of business at Henkelstraße 67, 40589 Düsseldorf, Germany.

RELATED APPEALS AND INTERFERENCES

Appellants are aware of the appeal in co-pending U.S. patent application serial number 09/923,626, pending before Examiner Qazi in Group Art Unit 1616, which may directly affect or may be directly affected by or may have a bearing on the Board's decision in the instant appeal. Appellants are not aware of any other related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

STATUS OF THE CLAIMS

Claims 1-32 are pending in the instant application on appeal. Claims 1-9 and 13-31 are the subject of the instant appeal. Claims 1-3, 6-9 and 13-31 stand finally rejected under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 5,703,252 of Hunt, *et al.* (hereinafter referred to as "Hunt '252"), in combination with U.S. Pat. No. 5,670,669 of Hunt, *et al.* (hereinafter referred to as "Hunt '669"), for the reasons of record set forth in Paper No. 10. Claims 4 and 5 stand finally rejected under 35 U.S.C. §103(a), as being unpatentable over Hunt '252 and Hunt '669, further in view of U.S. Pat. No. 6,448,423 of Hernandez, *et al.* (hereinafter referred to as "Hernandez"), for the reasons of record set forth in Paper No. 10. Claims 10-12 and 32 are objected to, but have been indicated as allowable if rewritten in independent form.

STATUS OF AMENDMENTS

No amendments have been filed in the instant application on appeal subsequent to the Examiner's final rejection of claims 1-9 and 13-31. Appellants' Request for Reconsideration After Final, filed on October 14, 2003 ("the Request for Reconsideration After Final"), has been considered but was not deemed to place the instant application in a condition for allowance, as

indicated in Paper No. 12. An appendix containing a copy of the claims involved in the appeal, in accordance with 37 C.F.R. §1.192(c)(9), is attached as Appendix A.

SUMMARY OF THE INVENTION

Appellants' invention is directed to sterol production and more particularly to a process for the production of sterols from residues from fatty acid production.. (*See*, Appellants' Specification, p. 1, lines 23-25). Appellants' claimed invention provides an economically and environmentally favorable process for the production of high-quality sterols, which is an improvement over the prior art. (*See, id.* at p. 1, lines 18-21 & p. 2, lines 23-26).

Appellants have discovered that a process for the production of sterols from fatty acid production residues can be achieved in an economical and environmentally-friendly by combining two separate transesterification steps. (*See, id.* at p. 2, lines 1-10). In the first transesterification step, the mono-, di- and triglycerides present after the esterification of the free fatty acids present in the residues are reacted under mild conditions with a lower alcohol in the presence of a basic catalyst. Under these mild conditions, the sterol esters remain predominantly bound and only a small amount of free sterols is formed (< 1% by weight). (*See, id.* at p. 2, lines 26-30). Following the first transesterification, and after removal of the excess alcohol, transesterification catalyst and glycerol, the fatty acid esters are distilled, resulting in concentration of the sterol esters at the bottom of the column. In a second transesterification step carried out under more extreme conditions, the sterol esters are then split into the free sterols. (*See, id.* at p. 3, lines 2-6). Because the impurities have been removed from this second transesterification step and the sterol esters are present in concentrated form, the free sterols can be obtained under far more economic conditions. (*See, id.* at p. 3, lines 6-9).

More specifically, one embodiment of Appellants' claimed invention is directed to processes for producing sterols, the processes comprising:

- (a) providing a fatty acid production-residue, said residue comprising sterol esters, free fatty acids, and partial glycerides;
- (b) removing the free fatty acids;

- (c) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst under mild transesterification conditions to form fatty acid alkyl esters and glycerol;
- (d) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and
- (e) transesterifying the sterol esters at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours to form free sterols.

(See, Appendix A of this Brief on Appeal, claim 1).

As explained above and in Appellants' Specification, Appellants' claimed invention provides an economical and ecologically improved process which begins with a fatty acid production residue containing sterol esters, free fatty acids and partial glycerides. The free fatty acids are first removed from the residue and then the residue is subjected to a *first* mild transesterification to form fatty acid alkyl esters and glycerol. These components can then be removed, for example, via distillation. The remaining sterol esters can then be subjected to a *second* transesterification apart from the original complex mixture present in the residue. Appellants' invention is a significant improvement over the prior art processes.

ISSUES

- (1) Does the term "mild", as defined in Appellants' Specification, as used in the claim phrase "mild transesterification conditions" impart meaning to the phrase such that the claim reads on less than 'any transesterification condition'?
- (2) Is the combined disclosure of the Hunt '252 reference and the Hunt '669 reference insufficient to establish a *prima facie* case of obviousness with respect to the claimed invention set forth in claims 1-3, 6-9, and 13-31?
- (3) Is the combined disclosure of the Hunt '252 reference, the Hunt '669 reference and the Hernandez reference insufficient to establish a *prima facie* case of obviousness with respect to the claimed invention set forth in claims 4 and 5?

GROUPING OF THE CLAIMS

All of the rejected claims stand or fall together for the purposes of the instant appeal.

ARGUMENT

I. The Examiner's Interpretation of the Claims is Incorrect

A. The Examiner's Interpretation:

In Paper No. 10, the Examiner notes that the claims recite a first transesterification under mild transesterification conditions. However, the Examiner has argued that "the instant claims lack definition of what 'mild transesterification conditions' are and, thus, are read to include any transesterification condition, including those taught by Hunt." (*See*, Paper No. 10, p. 2). The Examiner goes on to argue that while "the claims are read in light of the specification, limitations disclosed in the specification are not read into the claims." (*See, id.* at p.3). On this basis, the Examiner ignores the word "mild" in the claims and the portion of the Specification directed to its meaning.

B. Appellants' Traversal:

In Appellants' Request for Reconsideration After Final, Appellants respectfully disagreed with the Examiner's arguments and contentions in this regard.

Appellants again strenuously, but respectfully, traverse the Examiner's interpretation of the claim terms and the contentions and arguments in support thereof, for the reasons set forth below.

C. Law Regarding the Use of Intrinsic Evidence to Interpret Claim Terms:

As the Examiner has correctly noted in Paper No. 10, limitations disclosed in a specification are not to be read into the claims as claim limitations. However, it is incorrect to assert that a specification cannot be *used* to define a term or phrase explicitly set forth in a claim

and discussed in the specification. The M.P.E.P. specifically states that, "... when the specification provides definitions for terms appearing in the claims, ... the specification can be used in interpreting claim language." (*See*, M.P.E.P. 8th ed., §2111.01 citing *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970)).

D. Proper Claim Meaning:

Appellants submit that the term "mild" clearly and explicitly appears in the claims in reference to the transesterification conditions of the first transesterification step. (*See*, Appendix A of this Brief on Appeal, claim 1, subsection (c)). Appellants further submit that this term, "mild", carries a meaning, as do all claim terms. Furthermore, the meaning of the term, beyond its plain meaning (*i.e.*, gentle; not harsh), is not explicitly set forth in claim 1. However, to the extent the term's plain meaning doesn't provide a useful definition, Appellants' Specification describes and explains the meaning of "mild transesterification conditions". As set forth in Appellants' Specification,

[t]he [first] transesterification reaction takes place under mild conditions which may be established through the reaction temperatures or through the reaction time. Preferred conditions are temperatures T of 90 to 145°C, pressures p of 2 to 10 bar and more particularly 3 to 5 bar and reaction times of 2 to 20 minutes. (*See*, Appellants' Spec., p. 6, lines 26-29).

Accordingly, Applicants submit that "mild transesterification conditions" are defined, by the Specification. Furthermore, resort to the Specification is entirely permitted in defining a term which explicitly appears in the claim, such as "mild" in the instant claims on appeal.

Accordingly, Appellants submit that the Examiner has improperly ignored a claim term and has further improperly refused to give any weight to the definition of the term set forth in Appellants' Specification. Appellants respectfully request that the honorable Board consider the foregoing arguments and acknowledge the claim term "mild" in comparing the claims to the prior art.

II. The Examiner's Rejections Under 35 U.S.C. §103(a) are Improper

A. The Rejection of Claims 1-3, 6-9 & 13-31 Over Hunt '252 and Hunt '669:

In Paper No. 12, the Examiner maintains the rejection of claims 1-3, 6-9 and 13-31 under 35 U.S.C. §103(a), as being unpatentable in view of Hunt '252 and Hunt '669, for the reasons of record in Paper No. 10, and makes the rejection final.

In Paper No. 10, the Examiner acknowledges that the claimed first transesterification step is performed "under mild transesterification conditions." (See, Paper No. 10, pp. 2-3). However, the Examiner argues that "the instant claims . . . are read to include any transesterification condition, including those taught by Hunt." (See, Paper No. 10, p. 2). On this basis, the Examiner argues that the first transesterification step recited in the pending claims reads on conditions disclosed by the prior art and that the claimed process is obvious.

B. The Rejection of Claims 4 & 5 Over Hunt '252, Hunt '669 & Hernandez:

In Paper No. 12, the Examiner maintains the rejection of claims 4 and 5 under 35 U.S.C. §103(a), as being unpatentable in view of Hunt '252, Hunt '669, and Hernandez, for the reasons of record in Paper No. 10, and makes the rejection final.

In Paper No. 10, the Examiner, referring to Paper No. 8, contends that the Hunt references disclose the claimed invention as discussed in connection with the previous rejection, except for the utilization of sodium metasilicate, precipitation and separation for the removal of the free fatty acids. (See, Paper No. 10, p. 3; Paper No. 8, p. 4). However, the Examiner argues that Hernandez discloses the use of silicate solutions for the removal of fatty acids from crude vegetable oils. (See, *id.*). On this basis, the Examiner argues that claims 4 and 5 are obvious.

C. Appellants' Traversal:

Appellants respectfully traversed the Examiner's rejections in the Request for Reconsideration After Final, and initially in Appellants' Request for Reconsideration, filed on May 7, 2003, in response to Paper No. 8.

Appellants again strenuously, but respectfully, traverse the Examiner's rejections and the contentions and arguments in support thereof, for the reasons set forth below.

D. Law Regarding Prima Facie Obviousness:

In order for an Examiner to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner must show all of the following three criteria: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

E. Lack of Prima Facie Obviousness:

Appellants respectfully submit that none of the three requirements for establishing a *prima facie* case of obviousness has been satisfied based upon the cited references. The Hunt references fail to teach or suggest each and every element of Appellants' claimed invention. The Hunt references do not contain any teaching or suggestion which would motivate one of ordinary skill in the art to modify their teachings as needed to arrive at the claimed invention. Finally, neither reference contains any teaching or suggestion which would provide one of ordinary skill in the art with a reasonable expectation of successfully preparing sterols by deviating from the express teachings thereof. Hernandez fails to remedy any of these deficiencies.

Appellants submit that the "mild transesterification conditions" recited in the claims, as defined by the Specification, do not read on the prior art

Appellants' claimed invention is directed to processes for producing sterols which comprise: (a) providing a fatty acid production-residue comprising sterol esters, free fatty acids, and partial glycerides; (b) removing the free fatty acids; (c) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst *under mild transesterification conditions* to form fatty acid alkyl esters and glycerol; (d) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters;

and (e) transesterifying the sterol esters at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours to form free sterols.

Neither Hunt '252, nor Hunt '669, nor a combination of the two references, teaches a process for producing sterols wherein a first transesterification is performed under the claimed mild conditions, wherein very little sterol ester is converted to free sterol. Hunt '252 teaches the transesterification of the partial glycerides present in the starting material at temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, e.g. about 1 to about 3 hours", under pressure. (See, Hunt '252, col. 5, lines 20-24). These conditions are not mild as claimed.

The differences between these relatively harsh transesterification conditions disclosed in the Hunt references and the "mild" transesterification conditions employed in the first transesterification according to Appellants' claimed invention are evidenced in at least three different ways.

- ◆ First, the conditions disclosed in Hunt '252, as set forth above, are different than the conditions which are set forth in Appellants' Specification as being mild.
- ◆ Second, upon reviewing Hunt '252, one can see that the second transesterification disclosed therein, the transesterification of the sterol esters, is conducted under the same conditions as the first transesterification disclosed therein, namely temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, e.g. about 1 to about 3 hours", under pressure. (See, Hunt '252, col. 6, lines 24-28). Hunt '252 discloses two transesterifications performed under identical conditions. Based upon the fact that the first transesterification is conducted under the same conditions disclosed for the transesterification of the sterol esters, it is clear that sterol esters are transesterified during the first transesterification disclosed in Hunt '252 as well. Accordingly, it is clear that the first transesterification disclosed in Hunt '252 is different than the mild transesterification of Appellants' claimed invention wherein very little sterol ester is transesterified.

- ◆ Third, Hunt '669 specifically discloses that in the pre-esterification/transesterification portion of the process disclosed therein that, "the sterol fatty acid ester is reacted to sterol and fatty acid methyl ester." (See, Hunt '669, col. 6, lines 58-62). Again, under Appellants' claimed mild transesterification conditions, the sterol esters remain predominantly bound and only a small amount of free sterols is formed (< 1% by weight). (See, Appellants' Spec, p. 2, lines 26-30).

Accordingly, as the Hunt references fail to teach or suggest each and every element of the claimed invention, fail to motivate modification of their teachings such that one of ordinary skill in the art would arrive at the claimed invention, and fail to provide one of ordinary skill in the art with a reasonable expectation of success, Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the Hunt references.

Appellants also submit that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claims 4 and 5 based upon the Hunt references and Hernandez. As described above, the combined Hunt references fails to establish a *prima facie* case of obviousness. The Hernandez reference fails to remedy the deficiencies of the Hunt references. None of the references teaches the dual transesterification wherein the first transesterification is conducted under mild conditions.

Given the lack of any teaching or suggestion to modify the references in order to arrive at the claimed invention, and that fact that the references otherwise fails to teach or suggest each and every element of the claimed invention, one of ordinary skill in the art would find no reasonable expectation of successfully achieving the claimed invention based on the teachings of the cited references.

Accordingly, Appellants submit that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied.

Consideration by the Honorable Board and reversal of the Examiner's rejections of claims 1-9 and 13-31 under §103(a) are respectfully requested.

CONCLUSION

In view of the arguments set forth above, Appellants submit that the Examiner's rejections under 35 U.S.C. §103(a) are improper in that the Examiner has failed to establish a *prima facie* case of obviousness, and that all claims on appeal patentably distinguish over the prior art of record and known to Appellants, either alone or in combination. Accordingly, Appellants respectfully request that the Board find for Appellants and reverse the Examiner's final rejections.

Respectfully submitted,

GERHARD WOLLMANN, et al.

March 15, 2004
(Date)

By: _____

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APPENDIX A



Claims Pending in the Instant Application On Appeal:

1. A process for producing sterols, said process comprising:
 - (a) providing a fatty acid production-residue, said residue comprising sterol esters, free fatty acids, and partial glycerides;
 - (b) removing the free fatty acids;
 - (c) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst under mild transesterification conditions to form fatty acid alkyl esters and glycerol;
 - (d) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and
 - (e) transesterifying the sterol esters at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours to form free sterols.
2. The process according to claim 1, wherein the fatty acid production-residue is vegetable oil-derived.
3. The process according to claim 1, wherein the fatty acid production-residue comprises a residue derived from an oil selected from the group consisting of soybean oil, sunflower oil, rapeseed oil, coconut oil, palm oil, palm kernel oil, and mixtures thereof.
4. The process according to claim 1, wherein removing the free fatty acids comprises neutralization, precipitation and separation.

5. The process according to claim 4, wherein the free fatty acids are neutralized with a sodium metasilicate to form a precipitate, and the precipitate is separated by filtration.

6. The process according to claim 1, wherein removing the free fatty acids comprises esterifying the free fatty acids with a lower monohydric alcohol to form free fatty acid-based fatty acid alkyl esters, and removing the free fatty acid-based fatty acid alkyl esters with the fatty acid alkyl esters formed in step (d).

7. The process according to claim 1, wherein removing the free fatty acids comprises esterifying the free fatty acids with a polyol to form polyol esters, and transesterifying the polyol esters along with the partial glycerides transesterified in step (c).

8. The process according to claim 7, wherein the polyol comprises glycerol and the free fatty acids are esterified to form free fatty acid-based partial glycerides, and the free fatty acid-based partial glycerides are transesterified along with the partial glycerides transesterified in step (c).

9. The process according to claim 8, wherein esterification of the free fatty acids with glycerol is carried out at a molar ratio of about 1:1, at a temperature of from 215°C to 230°C, and at a pressure below 1 bar.

10. The process according to claim 1, wherein the transesterification of the partial glycerides under mild conditions is carried out at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar, for a period of from 2 to 20 minutes.

11. The process according to claim 1, wherein the transesterification of

the partial glycerides under mild conditions is carried out at a temperature of from 90°C to 145°C and a pressure of from 3 to 5 bar, for a period of from 2 to 20 minutes.

12. The process according to claim 8, wherein the transesterification of the partial glycerides under mild conditions is carried out at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar, for a period of from 2 to 20 minutes.

13. The process according to claim 8, wherein the transesterification of the partial glycerides under mild conditions is carried out at a temperature of from 90°C to 145°C and a pressure of from 3 to 5 bar, for a period of from 2 to 20 minutes.

14. The process according to claim 1, wherein the lower alcohol comprises methanol.

15. The process according to claim 1, wherein removing excess lower alcohol comprises allowing expansion until the reaction temperature has cooled to a temperature of from 65°C to 85°C.

16. The process according to claim 8, wherein the lower alcohol comprises methanol.

17. The process according to claim 8, wherein removing excess lower alcohol comprises allowing expansion until the reaction temperature has cooled to a temperature of from 65°C to 85°C.

18. The process according to claim 12, wherein the lower alcohol comprises methanol.

19. The process according to claim 12, wherein removing excess lower alcohol comprises allowing expansion until the reaction temperature has cooled to a temperature of from 65°C to 85°C.

20. The process according to claim 1, wherein the removal of the basic catalyst comprises the addition of an aqueous solution of an acid, precipitation of the catalyst and separation of the precipitate.

21. The process according to claim 1, wherein the fatty acid alkyl esters are removed by distillation.

22. The process according to claim 21, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

23. The process according to claim 14, wherein the fatty acid alkyl esters are removed by distillation.

24. The process according to claim 23, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

25. The process according to claim 16, wherein the fatty acid alkyl esters are removed by distillation.

26. The process according to claim 25, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

27. The process according to claim 18, wherein the fatty acid alkyl esters are removed by distillation.

28. The process according to claim 27, wherein the distillation is carried out at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar.

29. The process according to claim 1, wherein the transesterification of the sterol esters is carried out at a temperature of from 120°C to 130°C and at a pressure of from 3 to 6 bar, for a period of from 4 to 8 hours.

30. The process according to claim 1, further comprising purification of the free sterols via crystallization and washing.

31. The process according to claim 1, further comprising subjecting the free sterols to droplet formation via melting, spraying through droplet-forming nozzles, and solidification via cooling with countercurrent airflow in a gravity tower, to form dust free spherical particles.

32. A process for producing sterols, said process comprising:

(a) providing a fatty acid production-residue derived from an oil selected from the group consisting of soybean oil, sunflower oil, rapeseed oil, coconut oil, palm oil, palm kernel oil, and mixtures thereof, said residue comprising sterol esters, free fatty acids, and partial glycerides;

(b) esterifying the free fatty acids with glycerol to form free fatty acid-based partial glycerides;

(c) transesterifying the partial glycerides and the free fatty acid-based partial glycerides with methanol in the presence of a basic catalyst at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar, for a period of from 2 to 20 minutes, to form fatty acid methyl esters and glycerol;

(d) removing excess methanol, the basic catalyst, and the glycerol,

and distilling off the fatty acid methyl esters at a temperature of from 170°C to 200°C and a pressure of from 1 to 5 mbar, to form a bottom product comprising the sterol esters; and

(e) transesterifying the sterol esters at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours to form free sterols.